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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/751,276	SCARAMPI ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 37-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and declaration under 37C.F.R. 1.132, both filed 02/12/2009.

Claims 2-36 have been canceled, and claims 37-40 have been added.

Claims 1, 37-40 are pending and included in the prosecution.

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,001,688 ('688) in view of US 7,074,392 (392).

CA '688 teaches topical composition for treating human nails comprising 6.25% Gilsonite, mineral oil carrier that reads on excipients and enhancers, preservative, and 3% of soybeans that reads on the bioactive agent and enhancers (page 3, 1st paragraph; page 5, 3rd full paragraph; page 6, 1st paragraph; page 8, 2nd and 4th paragraphs). Gilsonite with mineral oil carrier expected to form gilsonite oil since gilsonite is soluble in hydrocarbon solvent (mineral oil) and because compounds and their properties are inseparable. CA '688 further teaches the composition further comprising antibacterial and antifungal agents (page 3; page 5, last paragraph; page 6, 3rd paragraph).

The expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition,

i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

Although CA '688 suggested bioactive agents including antibacterial agent in the composition applied to the nails, however, does not explicitly teach hydrocortisone, nicotine, or caffeine as instantly claimed by claim 1.

US '392 teaches sustained release nail treating composition comprising antibacterial agents and antipsoriatic agent, with hydrocortisone is preferred antipsoriatic agent in an amount of 0.1-10% (abstract; col.3, lines 36-39; col.4, lines 46-50; col.14, lines 45-49). The composition is suitable to treat nail and surrounding tissues and it reduces the unwanted side effects caused by high concentration of the antimicrobial agents (col.3, lines 24-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails comprising Gilsonite and antimicrobial agent as disclosed by CA '688, and further add hydrocortisone to the antimicrobial agent or replace antimicrobial agent with hydrocortisone disclosed by US '392according to the condition to be treated. One would have been motivated to do so because US '392 teaches that antimicrobial agents can be administered with hydrocortisone to the nails and further teaches that hydrocortisone is one of the preferred active agents to treat psoriasis of the nails and surrounding tissues and composition comprising hydrocortisone reduces the unwanted side effects caused by high concentration of the antimicrobial agents. One would reasonably

expected formulating topical composition for treating human nails comprising Gilsonite and antimicrobial agent and/or hydrocortisone that successfully treats the nail and surrounding tissues without any unwanted side effects.

4. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,001,688 ('688) in view of US 7,074,392 ('392) and further in view of US 5,562,642 ('42).

The combined teaching of CA '688 and US '392 are previously discussed as set forth in this office action.

CA '688 however does not specifically teach the viscosity and the specific gravity of Gilsonite oil as instantly claimed by claim 37. CA '688 does not specifically teach the amount of the oil in the composition. However, one having ordinary skill in the art would have been able to determine the viscosity and specific gravity of oil used in the topical composition as well as the amount of oil according to its specific intended use, drug used and site of application.

US '642 teaches cosmetic composition comprising oils that soften the skin and provide degree of barrier against the environmental irritants, the oils preferred to have viscosity between 35-70 cps and specific gravity between 0.8 and 0.9 (col.3, line 65 till col.6, line 19).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails comprising Gilsonite and hydrocortisone as disclosed by CA '688 combined with US

'392, and select the oil having viscosity between 35 and 70 cps and specific gravity between 0.8-0.9 as disclosed by US '642. One would have been motivated to do so because US '642 teaches that cosmetic compositions comprising oils having such properties soften the skin and provide degree of barrier against the environmental irritants. One would reasonably expected formulating topical composition for treating human nails comprising Gilsonite oil having viscosity between 35 and 70 cps and specific gravity between 0.8-0.9 and hydrocortisone wherein the composition having softening effect on the skin and barrier protection against the environment.

Response to Arguments

5. Applicant's arguments filed 02/12/02009 have been fully considered but they are not persuasive.

Applicants argue that Orlowski reference (CA '688) does not teach Gilsonite, rather suspension of Gilsonite ore in mineral oil in combination with other ingredients. CA '688 does not teach the specific Gilsonite oil and its range in the composition.

In response to this argument, it is argued that by Applicant's own admission, gilsonite is soluble in aliphatic, aromatic and chlorinated hydrocarbon solvents. CA '688 discloses Gilsonite in mineral oil carrier. By the broadest reasonable interpretation, the gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitably lead to some if not all of the gilsonite solubilizing into mineral oil to form gilsonite oil. Further, gilsonite oil is a component of gilsonite, therefore when gilsonite is dissolve in the hydrocarbon solvent, the gilsonite oil will be present. With regard to the amount of

Gilsonite oil, one having ordinary skill in the art would have been able to determine such amount according to the drug used. In any event the reference disclosed 6.25% Gilsonite. The amount of Gilsonite in the composition can be adjusted by person of ordinary skill in the art according to the drug used, specific intended use and site of application. Regarding the specific oils, in view of the new ground of rejection, the art recognized the claimed value of viscosity and specific gravity of oils as preferred properties of oils used in cosmetics.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicants further argue that US '392 fails to cure the deficiencies of CA '688 as the reference does not teach Gilsonite oil of specified composition in the specified range.

In response to this argument against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The invention as a whole as claimed by claim 1 is taught by the combination of CA '688 and US '392, and as claimed by claims 37-40 by the combination of CA '688, US '392 and US 642, as set forth in this office action.

Response to Amendment

6. The declaration under 37 CFR 1.132 filed 02/22/2009 is insufficient to overcome the rejection of claim 1 based upon U.S.C. 103 (a) over the combination of CA '688 and US '392, and the rejection of claims 37-40 based upon U.S.C. 103 (a) over the combination of CA '688, US '392 and US '642 as set forth in the last Office action because: It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue

of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. Further Gilsonite disclosed by CA '688 with mineral oil, as disclosed above Gilsonite ore in the presence of a hydrocarbon solvent (mineral oil) would inevitable lead to some if not all the Gilsonite solubilizing into solution, thereby all the oil of the Gilsonite would be extracted into the composition in the form Gilsonite oil including all the grades. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Applicants argue that the declaration demonstrates that the Gilsonite oil of instant claim 37 and its dependent claims is present in Gilsonite ore in concentrations of only about 0.1 weight percent. Orlowski uses Gilsonite ore suspended in mineral oil. Thus, it would not be possible for the Orlowski formulation to have even 0.1 weight percent Gilsonite oil, much less an amount substantially greater than that, and particularly of the Gilsonite oil specified.

In response to this argument, it is argued that the declaration does not show unexpected results obtained from the claimed range over that provided by the prior art, or unexpected results obtained from the specified Gilsonite oils. The prior art performed the same function of the present invention which is topical composition delivering active agents to the skin. One having ordinary skill in the art would have determined the desired amount of the oil in the composition according to the specific intended use, the property of the drug to be delivered and the specific site of application.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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